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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,715	09/05/2003	Yang-Dar Yuan	600-69-CIP	8271

7590 06/16/2006

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EXAMINER

LEWIS, AMY A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,715

Applicant(s)

YUAN ET AL.

Examiner

Amy A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-27,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-27,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/11/2006.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the Case

The Amendment and Remarks, filed 6 March 2006, have been entered into the application. Accordingly, claims 10, 16, 24 and 26 have been amended and claims 1-9 and 28-32 have been cancelled. Claims 10-27, 33 and 34, as filed 6 March 2006, are presented for examination.

Information Disclosure Statement:

The Allegretto et al. and the Cheng et al. references cited on the 11 May 2006 Supplemental Information Disclosure Statement were not provided by the Applicant and are therefore not considered.

Response to Applicants' Arguments/Remarks:

Applicants' arguments, filed 6 March 2006, have been fully considered but they are not deemed persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting:

1) The provisional rejection of claims 1-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-44, 46-77, and 79-89 of copending Application No. US 2003/0207931 (Vasudevan et al.), also Application Serial No.

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10/389071, has been *withdrawn* in view of the terminal disclaimer, filed on 9 February 2006 and approved on 9 February 2006.

2) The rejection of claims 28-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of US Pat. 6,740,676, has been *withdrawn* in view of the terminal disclaimer, filed on 9 February 2006 and approved on 9 February 2006.

Claim Rejections - 35 USC § 112, 2nd paragraph

4) Rejection of claims 1-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding the term “retinoids”, has been withdrawn in view of Applicants’ arguments.

5) Rejection of claims 17-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding hydrogen in the R₂ location, has been *withdrawn* in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

6) Rejection of claims 1-9 and 28-32 under 35 U.S.C. 102(b) as being anticipated by Granger et al. US Patent Application No. US 2004/0043044 A1 has been *withdrawn* in view of amendments to the claims.

NEW/MODIFIED GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112, 1st paragraph: scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7) Claims 10-27, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the enzyme P450RA with the claimed compounds *in vitro*, and for a method of treating the skin disorder plaque psoriasis in a mammal by administering the CP450RAI inhibitor liarozole or retinoic acid, does not reasonably provide enablement for preventing or treating *any* condition treatable by a retinoid or controlled by the mammal's native retinoic acid with the claimed compounds co-administered with a retinoid or a compound having vitamin a activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection is moot regarding claims 1-9 due to their cancellation. This rejection is ***maintained*** over claims 10-27 and ***newly applied*** to claims 33 and 34, for the reasons of record in the office action dated 4 November 2005 and further below.

Applicant argues that the rejection is "in error and should not be maintained" because the "claims in issue do not recite any specific disease [and] they are drawn to inhibiting the enzyme CP450RAI" and that the compounds of category 1 inhibit the enzyme is adequately demonstrated in the specification (Remarks p. 18, 3rd full

paragraph). It is noted that Applicant does not address the issue of lack of enablement for prevention.

The Examiner acknowledges that the claims do not recite specific diseases, as admitted by Applicant. However, the claims do recited the limitation “to prevent, treat or delay the onset of a disease or condition that is prevented, treated or the onset of which is delayed by...” see claim 10 for example). In response, and as stated in the previous office action and reiterated below, the Applicant fails to provide the guidance and information required to ascertain which *particular* type of retinoic acid related disease the claimed compounds agent will be effective against without resorting to undue experimentation.

The Examiner maintains that the specification does not enable any person skilled in the art to which it pertains (i.e. treatment and prevention of retinoic acid related diseases) to make or use the invention commensurate in scope with the claims. Applicants fail to provide the guidance and information required to ascertain which particular type of retinoic acid related disease the claimed compounds agent will be effective against without resorting to undue experimentation. And absent a reasonable *a priori* expectation of success for using the claimed compounds to treat any particular type of retinoic acid related disorder, one skilled in the art would have to extensively test many various diseases with the claimed compounds. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would

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be required to practice the invention as its is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

In addition, the burden of enabling the prevention of a retinoic acid related condition such as psoriasis for example, would be much greater than that of enabling the treatment of the condition. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing conditions related to retinoic acid or how a patient could be kept from every being susceptible to this condition. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active agents for preventing such conditions.

The term “prevention” is synonymous with the term “curing” and both circumscribe methods of absolute success. Since absolute success is not reasonably possible with most diseases/conditions, especially those having etiologies and pathophysiological manifestations as complex as retinoic acid related disorders (for example psoriasis), the specification, which lacks an objective showing that diseases potentially treatable with retinoids can actually be prevented, is viewed as lacking an adequate written description of the same.

Conclusion

Claims 10-27, 33 and 34 are rejected. No claims are allowed. This action is made NON-FINAL due to the new/modified grounds of rejection.

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Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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